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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,985	01/17/2002	Nicholas R. Bachur JR.	P-5478	3233
7590	08/11/2004		EXAMINER	
David W. Highet Becton Dickinson and Company Intellectual Property Department Mail Code 089 Franklin Lakes, NJ 07417-1880			STOCK JR, GORDON J	
			ART UNIT	PAPER NUMBER
			2877	
DATE MAILED: 08/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,985

Applicant(s)

BACHUR, NICHOLAS R.

Examiner

Gordon J Stock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-12 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-12 and 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the lack of antecedent basis in claim 9: “polymer, glass bead, or crystalline bead.”

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1-6, 9-12, 14-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Oberhardt (6,251,615)—cited by applicant** further in view of **Johnson (6,765,656)** and **Ambrose et al. (6,309,886)**.

As to **claims 1 and 11**, Oberhardt discloses a flow cell through which a specimen containing particles to be analyzed is caused to flow; an illumination source for illuminating an image capturing zone; an imaging optic; image capturing means; image processing means; wherein images are captured of particles flowing and captured in the flow cell within a capture cartridge by image capturing means and are analyzed. And a method is disclosed comprising: introducing a specimen containing particles of interest into an inlet port of a flow cell; moving the specimen from the inlet port to an imaging chamber of the flow cell; interrogating at least one field of view; and creating response files (col. 3, lines 55-67; col. 4; lines 1-50; Fig. 12: cols. 25-26; Fig. 1: col. 12, lines 10-40; col. 13, lines 48-67; col. 14, lines 25-45; Fig. 9b: col. 20, lines 45-67). (The embodiment relied upon is Fig. 12 in view of Fig. 1 for the flow of cells through

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the capture cartridge and in view of Fig. 9b for the structure of the capture cartridge.) As for producing still images, Oberhardt suggests this by stating that the camera captures signals of the individual cells (col. 27; lines 15-20). In addition, it is well known in the art that cameras take images in frames per second; whereas, a frame is one still image. Therefore, it would be obvious to one skilled in the art that still images are taken for a camera is used to capture the image.

In addition, Oberhardt discloses a blood sample is used of typically one microliter (col. 15, lines 10-12).

As for not having a sheath fluid, Oberhardt is silent. However, Johnson in an apparatus for imaging particles teaches using no sheath fluid (Fig. 2) in order to have illuminated volume not be required to have an intervening solvent, to be thin, nor does it need to be illuminated by a laser (col. 5, lines 35-45). And Ambrose in fluid analysis system teaches not having a sheath fluid to reduce sample adhesion to walls, sample degradation through interaction with walls, and reduce clogging events (col. 7, lines 1-10). Therefore, it would be obvious to one skilled in the art to have the system not use a sheath fluid in order to not have to use an intervening fluid solvent and to eliminate sample interactions with the walls such as adhesion, degradation through interaction, and clogging.

As for **claims 12 and 16**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 11**). In addition, Oberhardt discloses successive fields of view thereby at least one field of view is illuminated (col. 26, lines 49-60).

As for **claims 2 and 17**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claims 1 and 16**) and Oberhardt demonstrates a brightfield light source (Fig. 12).

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As for **claims 3 and 18**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claims 1 and 11**) and Oberhardt discloses a digital camera (col. 25, line 18).

As for **claim 4**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 1**) and Oberhardt discloses the transparency of the flow cell (Fig. 12).

As for **claim 5**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 1**) and Oberhardt discloses the flow cell comprising: an inlet port, an imaging chamber, an absorbent pad, a first channel connecting the inlet port to the imaging chamber and a second channel connecting the imaging chamber to the absorbent pad (Fig. 9b; col. 20, lines 45-67; col. 12, lines 10-45; col. 13, lines 48-67).

As for **claim 6**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 1**) Oberhardt discloses an incident light source (col. 25, lines 40-50).

As for **claims 20 and 24**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 11**) and Oberhardt discloses blood cells (col. 8, lines 54-65).

As for **claim 9**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 1**) and Oberhardt discloses polymer beads, latex beads (col. 15, lines 60-67).

As for **claim 10**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 1**) and Oberhardt discloses a microscope (Fig. 12, 70a).

As for **claims 14-15**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 11**) and Oberhardt discloses injecting the sample into the inlet port using a syringe and moving step is by syringe (col. 12, lines 15-30).

As for **claim 19**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 11**) and Oberhardt discloses staining the particles prior to introduction (col. 26, lines 30-40).

As for **claims 21-23**, Oberhardt in view of Johnson and Ambrose disclose everything as above (see **claim 20**) and Oberhardt discloses counting the particles; determining the DNA content of the particles; classifying the particles (col. 4, lines 40-50).

Response to Arguments

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

As for the applicant's arguments with the respect the objection to the specification with claim 9, Examiner does not find the argument persuasive, for applicant's disclosure on page 11 lines 1-3 solely mentions beads and not the particular material such as a polymer, glass, or crystalline material from which the beads are made.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

- 1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and
- 2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The

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form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (703) 872-9306

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431.

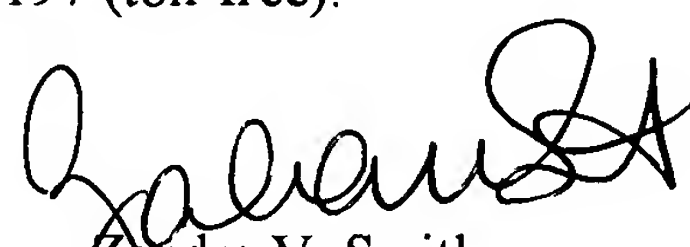
The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr., can be reached at 571-272-2800 ext 77.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


gs

August 2, 2004


Zandra V. Smith
Primary Examiner
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